

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: John N. STANIFORTH, et al.
Serial No.: To Be Assigned
Filed: Herewith
For: **PHARMACEUTICAL EXCIPIENT HAVING
IMPROVED COMPRESSIBILITY**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Alexandria, VA 22313-1450

April 2, 2004

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (5 sheets), enclosed herewith, for consideration by the Examiner in connection with the examination of the above-identified patent application.

The references cited in sheets 1-4 of the accompanying Form PTO-1449 are of record in Parent U.S. Application Serial No. 10/266,518. Accordingly, under 37 C.F.R. § 1.98(d), copies of these references are not enclosed.

The references cited in sheet 5 of the enclosed Form PTO-1449 are commonly assigned U.S. Patents, copies of which are enclosed.

The Examiner's attention is also directed to sheet 6 of the enclosed Form PTO-1449, which lists references cited by the Examiner during prosecution of Parent U.S. Application Serial No. 10/266,518. Accordingly, under 37 C.F.R. § 1.98(d), copies of these references are not enclosed.

Applicants respectfully advise the Examiner of the following U.S. Patents and Applications which are commonly assigned:

U.S. Patent No. 5,585,115; "Pharmaceutical Excipient Having Improved Compressibility", issued December 17, 1996;

U.S. Patent No. 5,725,883, "Pharmaceutical Excipient Having Improved Compressibility, issued March 10, 1998;

U.S. Patent No. 5,725,884, "Pharmaceutical Excipient Having Improved Compressibility, issued March 10, 1998;

U.S. Patent No. 5,741,524, "Pharmaceutical Excipient Having Improved Compressibility", issued April 21, 1998;

U.S. Patent No. 5,858,412, "Pharmaceutical Excipient Having Improved Compressibility", issued January 12, 1999;

U.S. Patent No. 5,866,166, "Pharmaceutical Excipient Having Improved Compressibility", issued February 2, 1999;

U.S. Patent No. 5,948,438, "Pharmaceutical Excipient Having Improved Compressibility", issued September 7, 1999;

U.S. Patent No. 6,395,303, "Process For Preparing A Directly Compressible Solid Dosage Form Containing Microcrystalline Cellulose", issued May 28, 2002;

U.S. Patent No. 6,103,219, "Pharmaceutical Excipient Having Improved Compressibility", issued August 15, 2000;

U.S. Patent No. 6,106,865, "Pharmaceutical Excipient Having Improved Compressibility", issued August 22, 2000;

U.S. Patent No. 6,471,994 "Pharmaceutical Excipient Having Improved Compressibility", issued October 29, 2002;

U.S. Patent No. 6,217,909 "Pharmaceutical Excipient Having Improved Compressibility", issued April 17, 2001;

U.S. Patent No. 6,521,261 "Pharmaceutical Excipient Having Improved Compressibility", issued February 18, 2003;

U.S. Patent No. 6,358,533 "Pharmaceutical Excipient Having Improved

Compressibility”, issued March 19, 2002;

U.S. Patent Application Serial No. 10/015,538, “Process For Preparing A Directly Compressible Solid Dosage Form Containing Microcrystalline Cellulose”, filed December 13, 2001;

U.S. Patent Application Serial No. 10/266,518, “Pharmaceutical Excipient Having Improved Compressibility,” allowed; and

U.S. Patent Application Serial No. 10/145,563, “Pharmaceutical Excipient Having Improved Compressibility”, filed May 14, 2002

U.S. Patent Application Serial No. 10/338,361, “Pharmaceutical Excipient Having Improved Compressibility”, filed January 8, 2003.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner’s attention is directed to Exhibit A, attached herewith, which contains the following:

(i) allowed claims of parent U.S. Patent Application Serial No. 10/266,518, which consists of the same specification as U.S. Patent no. 6,471,994, listed as referenced EB on the enclosed Form PTO-1449.

(ii) pending claims of U.S. Patent Application Serial No. 10/015,538, which consists of the same specification as U.S. Patent No. 6,395,303, listed as reference EH on the enclosed Form PTO-1449.

(iii) pending claims of U.S. Patent Application Serial No. 10/338,361, which consists of the same specification as U.S. Patent No. 6,103,219, listed as reference EA on the enclosed Form PTO-1449.

(iv) specification and pending claims of U.S. Patent Application Serial No. 10/145,563.

It is respectfully requested that the references cited on the accompanying Form PTO-1449 be considered and made of record. If any of the references listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

No fee is believed to be due for the submission of this Information Disclosure Statement as it is filed under 37 C.F.R. § 1.97(b), before the mailing of a first Office Action on the merits or within three (3) months of the actual filing date. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

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FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 541.1024CON2

SERIAL NO.: To Be Assigned

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): John N. STANIFORTH, et al.

FILING DATE: Herewith

GROUP: To Be Assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCL ASS	FILING DATE IF APPROPRIATE
	AA	3	0	2	3	1	0	4	2/27/62	Battista, et al.	99	1	
	AB	3	0	6	7	0	3	7	12/4/62	Herald, et al.	99	139	
	AC	3	5	3	9	3	6	5	11/10/70	Durand, et al.	CO8b	21/30	
	AD	3	5	7	3	0	5	8	3/30/71	Tiemstra, et al.	A231	1/00	
	AE	4	5	3	6	5	1	1	8/20/85	Fischer, et al.	A61K	31/415	
	AF	4	7	2	1	7	0	9	1/26/88	Seth, et al.	A61K	31/55	
	AG	4	9	1	0	0	2	3	3/20/90	Botzolakis, et al.	B61K	9/26	
	AH	5	0	3	0	4	0	0	7/9/91	Danielsen, et al.	B29B	9/08	
	AI	5	0	7	5	1	1	5	12/24/91	Brine	A61K	9/14	
	AJ	5	4	6	2	7	4	7	10/31/95	Radebaugh, et al.	A61K	9/24	
	AK	5	4	6	2	7	6	1	10/31/95	McGinley, et al.	A23L	1/0528	
	AL	5	5	0	5	9	8	2	4/9/96	Krawczyk, et al.	A23L	1/0534	
	AM	4	5	3	3	6	7	4	08/06/85	Schmidt, et al.	A61K	31/365	
	AN	5	5	6	0	9	2	6	10/01/96	Franz, et al.	A61K	9/20	
	AO	4	1	5	9	3	4	5	06/26/79	Takeo et al.	424	362	01/31/78
	AP	4	6	6	4	9	1	5	05/12/87	Simonian	424	128	02/21/86
	AQ	4	7	4	4	9	8	7	05/17/88	Mehra et al.	424	156	08/03/87
	AR	4	8	1	0	5	1	6	03/07/89	Kong-Chan	426	548	02/27/87
	AS	4	9	2	3	9	8	1	05/08/90	Weibel et al.	536	56	04/06/89
	AT	4	9	4	6	6	8	5	08/07/90	Edgren et al.	424	472	09/01/88
	AU	5	1	2	6	1	4	5	06/30/92	Evenstad et al.	424	465	06/11/90
	AV	5	1	9	2	5	6	9	03/09/93	McGinley et al.	426	96	12/18/91
	AW	5	4	4	1	7	5	3	08/15/95	McGinley et al.	426	96	01/28/94
	AX	5	3	2	2	6	9	8	06/21/94	Kovacs, et al.	A61K	9/36	06/05/92
	AY	3	1	4	1	8	7	5	07/21/64	Battista, O.			

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	BA	5	7	3	3	5	7	8	03/31/98	Hunter, et al.	424	489	11/15/87
	BB	5	8	5	8	4	0	9	01/12/99	Karetny, et al.	424	489	04/17/96
	BC	4	2	3	2	0	5	2	11/4/80	Nappen	A23D	5/00	
	BD	4	8	4	9	2	2	7	1/18/89	Cho	A61K	9/16	
	BE	5	0	1	9	3	9	7	5/28/91	Wong, et al.	A61K	9/24	
	BF	5	4	4	7	7	2	9	9/5/95	Belenduik, et al.	A61K	9/16	
	BG	5	4	4	1	7	3	1	8/15/95	Jaxa-Chamiec, et al.	A61K	31/74	
	BH	5	4	7	8	5	7	4	12/95	Baichwal, et al.	424	485	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBC LASS	TRANSLATION	
													YES	NO
	BI	1	4	6	4	2	0	0	02/09/77	Great Britain	A61K	31/505	N/A	
	BJ	1	4	8	0	1	8	8	07/20/77	Great Britain	A61K	9/16	N/A	
	BK	0	3	0	5	0	5	1	3/1/89	EP A1	A61K	9/22	N/A	
	BL	4	3	0	3	8	4	6	8/11/94	Germany A1	A61K	31/19		X
	BM	0	4	3	0	2	8	7	6/5/91	EP A2	A61K	9/52	N/A	
	BN	0	5	4	3	5	4	1	5/26/93	EP A1	A61K	31/165	N/A	
	BO	WO	95	3	5	1	0	4	12/28/95	PCT A1	A61K	31/19	N/A	
	BP	WO	92	0	3	1	2	6	3/5/92	PCT A1	A61K	9/20	N/A	
	BQ	WO	92	1	2	6	3	3	8/6/92	PCT	AO1N	25/10	N/A	
	BR	WO	90	1	4	0	1	7	11/29/90	PCT	A23L	1/0534	N/A	
	BS	WO	93	1	2	7	6	8	7/8/93	PCT	A61K	9/14	N/A	
	BT	WO	94	0	6	3	0	9	3/31/94	PCT	A23L	1/38	N/A	
	BU	WO	95	2	0	3	2	6	8/3/95	PCT	A23L	1/0534	N/A	

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 541.1024CON2				SERIAL NO.: To Be Assigned							
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)										APPLICANT(S): John N. STANIFORTH et al.							
										FILING DATE: Herewith				GROUP: To Be Assigned			
FOREIGN PATENT DOCUMENTS																	
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	CB	0	6	0	9	9	7	6	01/04/94	EP (A1)	CO8B	15/02	N/A				
	CC																
	CD																
	CE																
	CF																
	CG																
	CH																
	CI																
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)																	
	CJ	Machines Collette High Shear Mixer Granulator Promotional Literature (date unknown)															
	CK																
	CL																
	CM																
	CN																
	CO																
	CP																
	CQ																
	CR																
EXAMINER										DATE CONSIDERED							
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.																	

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	DA						
	DB						
	DC						
	DD						
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	DF						
	DG						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	DH						
	DI						
	DJ						
	DK						
	DL						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	DM	Bob Sherwood, US- 2003-0096005- Publication of US Application Serial No. 10/338,361, filed 01/08/2003					
	DN						
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	DP						
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*EXAMINER INITIAL	EA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	EA	5	5	8	5	1	1	5	12/17/96	Sherwood et al.	424	489		
	EB	5	7	2	5	8	8	3	03/10/98	Staniforth et al.	424	489		
	EC	5	7	2	5	8	8	4	0310/98	Sherwood et al.	424	489		
	ED	5	7	4	1	5	2	4	04/21/98	Staniforth et al.	424	489		
	EE	5	8	5	8	4	1	2	01/12/99	Staniforth et al.	424	489		
	EF	5	8	6	6	1	6	6	02/02/99	Staniforth et al.	424	489		
	EG	5	9	4	8	4	3	8	09/07/99	Staniforth et al.	424	464		
	EH	6	3	9	5	3	0	3	05/28/02	Staniforth et al.	424	499		
	EI	6	1	0	6	8	6	5	08/22/00	Staniforth et al.	424	489		
	EJ	6	2	1	7	9	0	9	04/17/01	Sherwood et al.	424	494		
	EK	6	5	2	1	2	6	1	02/18/03	Sherwood et al.	424	494		
	EL	6	3	5	8	5	3	3	03/19/02	Sherwood et al.	424	494		
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	EQ													
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	EA	6	1	0	3	2	1	9	08/15/00	Sherwood et al.	424	049		
	EB	6	4	7	1	9	9	4	08/27/99	Staniforth et al.	424	489		
	EC													
	ED													
	EE													
	EF													
	EG													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	EI													
	EJ													
	EK													
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